

# GENERAL REQUIREMENTS FOR LACF PRODUCTS

Thank you for your inquiry to the California Department of Health Services' Food and Drug Branch (FDB) Botulism Control and Cannery Inspection Program regarding your interest in producing a new thermally processed Low Acid Canned Food (LACF). By regulation a LACF product is defined as, "any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods."

The following steps and procedures must be followed to obtain a Cannery License and/or an Official Scheduled Process for a specific LACF product.

1. You must submit a completed Cannery License Application (Form DHS 8597) and appropriate license fee. The instructions will be attached to the form. You can download this form from the FDB website:  
<http://www.dhs.ca.gov/publications/forms/pdf/dhs8597.pdf>. If you already have a canner's license, then proceed to the instructions in the next step.
2. You must submit to the State's (FDB's) consulting laboratory, the University of California Laboratory For Research in Food Preservation (UCLRFP), a completed "Request for Official Sterilization Process" (pdf) form.

**University of California Laboratory  
For Research in Food Preservation  
6363 Clark Avenue  
Dublin, CA 94568-3097  
(925) 828-1790**

3. For each specific LACF product, you must submit to UCLRFP a detailed description of the product (including container specifications), thermal processing procedures and equipment specifications. You will need to describe in detail product formula and all ingredients, preparation methods and manufacturing procedures, including the batch formulation, temperatures, etc. Do not intermingle unit measurements for ingredients, such as weights in ounces and not in fluid ounces. It is preferable if you can list the percentage of each ingredient in the formula rather than the unit measurement.
4. You must keep a photocopy of the "Request for Official Sterilization Process" (pdf) form on file for the FDB investigator's inspection at a later date. *If there are any changes in your formula, equipment specifications and/or thermal processing procedures, you must re-submit this form and new procedures to UCLRFP for another possible evaluation.*

## **WHAT HAPPENS AFTER UCLRFP EVALUATION**

You, the applicant canner, will be advised of the results by a letter from FDB. During this time, please do not call UCLRFP to find out the results of your LACF product and thermal

process evaluation. After the initial review, the applicant canner will be contacted by phone and/or letter regarding any one, or combination of all, of the following possible outcomes:

- (a) A UCLRFP scientist will call and set-up a date and time to visit the canning facility to conduct a thermal process evaluation and/or product heat penetration study. A successful evaluation at this point will result in UCLRFP recommending product specific cook/process specifications to assure commercial sterility. FDB will in turn review the recommendations by UCLRFP and issued a product specific Official Scheduled Process that will be identified by a unique S-Number (S#).
- (b) The applicant canner may be asked by UCLRFP and/or FDB to submit additional information.
- (c) Based on a review by experts at UCLRFP, the applicant canner may be asked to hire an LACF thermal process and/or food safety consultant to provide further assistance in setting up a low acid food canning facility. This outcome can occur if the applicant canner does not have sufficient equipment specifications and/or thermal processing procedures in place for producing a commercially sterile LACF product.
- (d) California law requires that all operators of thermal processing equipment (e.g., various retorts and aseptic processing systems) be permitted after receiving a passing score on a written and practical test administered by FDB. FDB will require each LACF canner to submit a list of candidates for this test. The scheduling of this test is by appointment and must occur after the cannery license and Official Scheduled Process has been issued and the thermal processing equipment is fully operational.
- (e) By appointment, the applicant canner will be required to pass an on-site license inspection by an FDB investigator before a license is issued that demonstrates compliance with LACF laws and regulations. During the license inspection process, the FDB investigator will inspect for adequacy of facilities, equipment, personnel qualifications, personnel practices, manufacturing procedures and controls, overall sanitation, ingredients and raw materials, container coding, container integrity, labeling, production record keeping, storage and distribution processes, and registration with FDA. The FDB investigator will insure that each LACF product will meet its specific requirements in the Official Scheduled Process issued by FDB and identified by a unique S#. The S# is generated by the UCLRFP and maintained by FDB throughout the history of each specific LACF product. The FDB investigator will also insure that each lot/batch of LACF product is properly documented in pre-numbered and initialed production records. The production records and LACF cook charts MUST be numbered in sequence beginning with number 1 for the period July 1 through June 30 of the following year. The FDB investigator prior to actual production must perform the numbering and initialing of records so that these will be ready for the canner to use. The production records will document all critical data for each lot/batch of LACF product as required by the Official Scheduled Process, including name of canner, date of pack, product name, person(s) responsible for processing, total number of containers packed, container integrity testing records and distinct code for each product. The container code can consist of any combination of numbers or letters, which the following information must be identified: (a) the plant (or company) where product is processed; (b) the year of pack; (c) a distinct product

code; (d) the date of pack; and, (e) batch or cook code. (Please note: it is recommended that, unless there is a distinct batch manufactured, the batch number be changed every 2 hours.)

Please contact a supervisor at one of the FDB offices (see list below) to set up appointment for the new license inspection.

The applicant canner will be notified in writing by FDB of deficiencies and/or violations that would prohibit the issuance of a new cannery license.

**\*\*\*Cannery License Fee Waiver:** The cannery license fee may be waived if you can provide a valid California food processor registration. The registration is mandatory for all food processors and wholesalers of processed food (H&SC 110460).

### **OTHER REQUIREMENTS**

- LACF licensed canneries must comply with the Good Manufacturing Practices (GMP) requirements pursuant to [Title 21 Code of Federal Regulations Part 110](#), including the applicable sections of [Title 21 Code of Federal Regulations Part 113](#).
- You must develop an appropriate record system and retain all records as required by law and regulation for all LACF products. The California laws and regulations relating to the canning of LACF products are found in the [California Health and Safety Code Section 112650 et seq.](#) and [Title 17 California Code of Regulations Section 12400 et seq.](#)
- LACF canners must have permitted retort operators to operate their retort or aseptic systems. Operators are given written and practical examinations on equipment operation by the Food and Drug Branch. Upon successful completion of both exam components, operators will be issued the permit.
- You must develop a container coding system and apply the code to all containers produced as specified in law and regulation.
- Once you are licensed and have taken the above steps, you are required to notify FDB before you begin manufacturing the LACF product that requires the FDB release for shipment. To routinely release LACF product, an FDB investigator will arrange to inspect your facility, audit records and assure all LACF product(s) have met the requirements specified in the specific Official Scheduled Process before it can be released.
- You are required to notify the FDB investigator whenever you need a release of product, whenever any spoilage is noted, or if any foodborne illness has been reported. It is recommended that you notify the FDB investigator 48 hours in advance of any scheduled LACF processing.
- No batches of LACF product required to be produced under the Cannery Inspection Program can be sold or donated until they have been officially released by FDB. Violations of the law are subject to fines or imprisonment.
- Please note that the hourly inspection fees are charged for inspection and travel time for your facility. The canner will be billed on a monthly basis. As specified in law, the

Cannery Inspection Board establishes the hourly rate for inspection. The rate currently starts at approximately \$120 per hour.

- All fish and seafood products produced in a licensed cannery must also meet the federal [Hazard Analysis and Critical Control Point \(HACCP\)](#) requirements before the products will be released by FDB.
- All products should be produced under supervision of a person who has attended a Better Process Control School as specified in 21 CFR 114.10.
- You are also responsible to register your facility and LACF products you produce with the [U.S. Food and Drug Administration](#).

Upon the completion of the UCLRFP evaluation, if your product is not subject to the FDB's cannery inspection and product release, the processed food product must still be manufactured in a food processing facility registered with FDB's [Processed Food Registration Program \(PFR\)](#). Please call (916) 650-6500 for PFR registration information and application form.

Note: Regarding your LACF product formulation, equipment and thermal processing specifications submitted to UCLRFP and/or FDB for evaluation, your product formulation and specifications are protected under the law: State of California Health and Safety Code Section 110165. It is unlawful for any person to use to his own advantage, or to reveal to any person other than to the director or officers or employees of this department, or to the courts when relevant in any judicial proceeding under this division, any information acquired under authority of this division concerning any method or process which as a trade secret is entitled to protection.

For additional information and questions, please call or contact an FDB Supervisor at one of the following offices:

## **FOOD AND DRUG BRANCH OFFICES**

### **FDB Food Safety Inspection Unit – Northern Region**

100 Paseo de San Antonio, Room 304, San Jose, CA 95113  
Telephone: (408) 277-1832; Fax: (408) 277-1141

### **FDB Food Safety Inspection Unit – Southern Region**

1449 West Temple Street, Room 224, Los Angeles, CA 90026  
Telephone: (213) 580-5720; Fax: (213) 580-5750